DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3161. Misbranding of amphetamine hydrochloride tablets, dextro amphetamine hydrochloride tablets, and thyroid tablets. U. S. v. David Greenberg (Frank's Pharmacy). Plea of guilty. Fine, $500. (F. D. C. No. 29118. Sample Nos. 51679–K, 51686–K, 51693–K, 52125–K, 52146–K.)

INFORMATION FILED: May 1, 1950, Southern District of Ohio, against David Greenberg, trading as Frank's Pharmacy, Cincinnati, Ohio.

INTERSTATE SHIPMENT: On or about January 24 and February 3, 1949, from the States of Illinois and Michigan into the State of Ohio.

ALLEGED VIOLATION: On or about June 12, July 24 and 30, and August 5, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused certain quantities of the drugs to be repacked and sold to various persons, which acts resulted in the repackaged drugs being misbranded.

LABEL, WHEN SHIPPED: "Amphetamine HCl 10 mgs. per tablet," "Dextro Amphetamine HCl 5 mgs. per tablet," and "Thyroid Strong * * * 50% Stronger than U. S. P."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs failed to bear labels containing the name and address of the manufacturer, packer, or distributor; Section 502 (b) (2), the *amphetamine hydrochloride tablets* and the *dextro amphetamine hydrochloride tablets* failed to bear labels containing a statement of the quantity of the contents; Section 502 (e) (1), the *amphetamine hydrochloride tablets* and the *dextro amphetamine hydrochloride tablets* failed to bear labels containing the common or usual name of the drugs; Section 502 (f) (1), the directions "Use as Directed," borne on the labeling of the *thyroid tablets*, were not adequate directions for use; and Section 502 (f) (2), the *amphetamine hydrochloride tablets* and the *dextro amphetamine hydrochloride tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 12, 1950. A plea of guilty having been entered, the court imposed a fine of $500.

3162. Misbranding of sulfathiazole tablets and Seconal Sodium capsules. U. S. v. Peoples Pharmacy, Inc., and Samuel I. Pigurski. Pleas of nolo contendere. Fine of $150 plus costs, against defendants jointly. (F. D. C. No. 29114. Sample Nos. 60607–K to 60610–K, incl., 60613–K, 60614–K.)

INFORMATION FILED: April 25, 1950, Northern District of Indiana, against Peoples Pharmacy, Inc., Gary, Ind., and Samuel I. Pigurski, secretary-treasurer and pharmacist for the corporation.

INTERSTATE SHIPMENT: From the State of Illinois into the State of Indiana, of quantities of *sulfathiazole tablets* and *Seconal Sodium capsules*.

ALLEGED VIOLATION: On or about May 13, 18, and 23, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repackaged and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (e) (1), the repackaged *sulfathiazole tablets* failed to bear a label containing the common or usual name of the article.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which has been designated by regulations as habit forming; and when repackaged the capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged *Seconal Sodium capsules* bore no labeling containing directions for use; and Section 502 (f) (2), the *sulfathiazole tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 24, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of $150, plus costs, against the defendants jointly.

3163. Misbranding of sulfadiazine tablets and Seconal Sodium capsules. U. S. v. Max Capestany, Jr. (Central Pharmacy), and David Hernandez. Pleas of nolo contendere. Fine of $100 against defendant Capestany and $50 against defendant Hernandez, plus costs. (F. D. C. No. 29113. Sample Nos. 60601-K, 60603-K, 60604-K.)

INFORMATION FILED: April 25, 1950, Northern District of Indiana, against Max Capestany, Jr., trading as the Central Pharmacy, Gary, Ind., and David Hernandez, a pharmacist in the pharmacy.

INTERSTATE SHIPMENT: From the State of Illinois into the State of Indiana, of quantities of *sulfadiazine tablets* and *Seconal Sodium capsules*.

ALLEGED VIOLATION: On or about May 13 and 23, 1949, while a number of the above-mentioned tablets and capsules were being held for sale at the Central Pharmacy after shipment in interstate commerce, various quantities of the tablets and capsules were repacked and sold without a prescription, which acts resulted in the repackaged tablets and capsules being misbranded.

Max Capestany, Jr., was charged with causing the acts of repacking and sale of the drugs involved in each of the three counts of the information; and, in addition, David Hernandez was charged in count 1 with causing such acts to be done in connection with the drug involved in that count.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which has been designated by regulations as habit forming; and when repackaged, the capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the article; Section 502 (f) (1), all lots of the repackaged drugs failed to bear